IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

MYLAN PHARMACEUTICALS, INC.,	:	ELECTRONICALLY FILED
	:	
Plaintiff	:	
	:	Civil Action No. 1:05-CV-1416
v.	:	(Judge Rambo)
	:	
MERCK & CO., INC.,	:	
	:	
Defendant	:	

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS PLAINTIFF'S COMPLAINT

Dated: October 26, 2005

Respectfully submitted,

s/ Brian P. Downey

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INTRODUCTION

Defendant Merck & Co., Inc. ("Merck") submits this reply memorandum in support of its motion to dismiss the complaint for lack of subject matter jurisdiction.

In its Memorandum In Opposition, (Doc. 34, "Mylan memo"), Mylan essentially ignores the recent decision of the Court of Appeals for the Federal Circuit[2] in *Teva Pharmaceuticals USA, Inc. v. Pfizer*, 395 F.3d 1324 (Fed. Cir. 2005), *cert. denied*, No. 05-48, 2005 U.S. LEXIS 7632 (Oct. 11, 2005), the dispositive precedent on the issues presented by this motion. In addition, Mylan (a) crops a quotation from the *Teva* case and thereby distorts its meaning, (b) repeatedly cites a concurring opinion in a different decision, the reasoning of which has been rejected by Congress, (c) advances a view of the law which the Court of Appeals has rejected and (d) relies on a series of district court cases which are readily distinguishable and all of which were decided before *Teva*.

Mylan further misleadingly repeatedly tells the Court that Mylan's fear of being sued is supported by Merck's having sued a different generic company, but avoids mentioning that the other suit was for a different product

[2] Any appeal in this case would be heard by that Court. *Shell Oil Co. v. Amoco Corp.*, 970 F.2d 885, 888 n.4 (Fed. Cir. 1992).

from the one Mylan proposes to sell and that the patents there in suit are different from the ones against which Mylan has filed its paragraph IV certification.

The bulk of Mylan's opposition brief continues to argue the plainly sham position that Mylan fears being sued, and not until page 27 does it even attempt to justify its real purpose, which is to trump the marketing exclusivity of another generic company that filed its patent certification before Mylan did. As the *Teva* decision makes clear, this is not a situation that creates a justiciable controversy.

ARGUMENT

A. It Is Mylan's Burden To Demonstrate Jurisdiction

On a motion to dismiss for want of a case or controversy, the burden is on the plaintiff to establish subject matter jurisdiction. *McNutt v. General Motors Acceptance Corp.*, 298 U.S. 178 (1936); *Jervis B. Webb Co. v. Southern Sys. Inc.*, 742 F.2d 1388, 1398-99 (Fed. Cir. 1984). Mylan has utterly failed to discharge that burden.

B. Mylan Ignores Controlling Precedent

As pointed out in Merck's opening memorandum, the controlling precedent on the issues raised by this motion is the recent decision in the *Teva* case, in which the Court of Appeals rejected virtually every one of the arguments advanced by Mylan. Despite the obvious importance of the *Teva* decision to the

issues raised by this motion, Mylan does not even acknowledge it until page 22 of its memorandum and, even then, gives it only passing comment. Mylan's brief never discusses the facts of the *Teva* case and never tries to distinguish it.

Moreover, in that abbreviated discussion of *Teva*, Mylan crops a quotation to make it seem the Court said that the "two-part test" (*i.e.*, reasonable apprehension plus an act of infringement) is not the constitutional standard. What the court actually said was:

> *[T]he statement from Fina Oil upon which Teva relies follows the court's recognition of the traditional two-part test. 123 F.3d. at 1470. Under these circumstances, the statement at most suggests that* the traditional two-part test test is not the only way of determining in all cases that the constitutional requirement of an actual case or controversy has been met. *The statement in no way suggests that the traditional test does not address the Article III requirement of an actual controversy.*

Teva, 395 F.3d at 1335-36. The italicized portion of that quotation is what Mylan's memorandum omits – the phrase "at most suggests" and the last sentence which, taken together, demonstrate that the import of the court's discussion is very different from what Mylan's cropped quotation would suggest. If there were any doubt, the Court explicitly said:

> We do not think that the cases cited by Teva support the proposition that the reasonable apprehension of suit prong of our traditional two-part test is not a constitutional requirement.

Id. at 1335, and

> Whether an actual controversy exists between Teva and Pfizer turns on the reasonable apprehension of suit test, which remains in place under the Medicare Amendments, and we have concluded that, under that test, Teva has not established that an actual controversy exists between it and Pfizer.

Id. at 1338.

In support of its argument that this Court should ignore the clear, binding *Teva* precedent, Mylan cites *Stone v. INS*, 514 U.S. 386, 397 (1995) for the proposition that the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") broadened the standard and that "[w]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." This argument, however, assumes, first, that Congress intended to eliminate the "reasonable apprehension" test for determining whether Article III jurisdiction exists in an ANDA case and, second, that Congress had the power under the Constitution to amend the standard as Mylan proposes. Neither is true.

The Court of Appeals in *Teva* expressly examined the legislative history and found that there was no evidence that Congress intended the MMA to give the federal courts broadened subject matter jurisdiction. It quoted from the Conference Committee Report:

> Through the modifications in this Act, the conferees do not intend for the courts to modify their application of the requirements under Article III that a declaratory judgment plaintiff must, to the extent required by the Constitution, demonstrate a "reasonable

> apprehension" of suit to establish jurisdiction. (citing *Fina Oil and Chemical Co. v. Ewen*, 123 F.3d 1466, 1471 (Fed. Cir. 1997))

Id. at 1336-37, and it concluded that

> Neither do we think that in the Medicare Amendments Congress intended to cause courts to alter the present test for determining whether an actual controversy exists in the Hatch-Waxman setting. The plain language of the amended statute - that courts shall have subject matter jurisdiction "to the extent consistent with the Constitution" – compels the conclusion that the Amendments were not meant to automatically bestow district court jurisdiction over actions such as Teva's.

Id. at 1336. Thus, the intent which Mylan seeks to find in the action of Congress simply does not exist. And, of course, absent that intent, the reasoning of *Stone v. INS* does not apply.[3]

Second, *Stone v. INS* did not involve an issue of Constitutional dimensions. There was no argument in *Stone* that the amended statute, irrespective of which party's interpretation the Court adopted, was in any way in conflict with the Constitution. In the present case, by contrast, the interpretation for which Mylan contends would, in fact, render the Congressional action unconstitutional. Indeed, as the *Teva* decision demonstrates, an earlier version of the bill, which would have been more conducive to Mylan's position, was rejected in the

[3] That does not mean that the MMA lacks "real and substantial effect." Its effect, however, was to limit a generic's ability to bring declaratory judgment actions by requiring that it must first give the patent owner access to its ANDA as Mylan did. 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc).

Conference Committee Report specifically because of concerns about its constitutionality. *Id.* at 1336.

It is particularly significant to note that throughout its opposing memorandum, Mylan relies heavily on the concurring opinion of Judge Gajarsa in *Minnesota Mining & Mfg. Co. v. Barr Labs., Inc*., 289 F.3d 775, 784 (Fed. Cir. 2002).[4] First, since that was a concurring opinion it means that even the other two members of that panel did not adopt it. More importantly, the *Gajarsa* concurring opinion, as the Court of Appeals pointed out in *Teva*, corresponded to the MMA legislation as originally introduced, before it was modified to its more restrictive form in the Conference Committee Report. *Id*. at 1336. Thus, Mylan is trying to resurrect an opinion that was never precedential, and one that was effectively rejected by the Congress and by the *Teva* court.

Mylan's filing this action in the face of the *Teva* decision and its inability to deal with that controlling precedent, show that this complaint is frivolous and a waste of this Court's resources.

C. The Facts Here Are Virtually Indistinguishable From Those Of The *Teva* Case

In the *Teva* case, Teva, the ANDA filer, asserted a combination of factors to support its position that it had an objectively reasonable apprehension of

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[4] *See* Doc. 34, Mylan memo at 5, 8, 14 and 27.

being sued. On that combination of factors, the Court of Appeals held that there was no Article III jurisdiction. Mylan relies on the same combination of factors. In *Teva*, as here, the patentee, filed a new drug application ("NDA") with the FDA and listed patents in the FDA's Orange Book. *Teva*, 395 F.3d at 1331. In *Teva*, as here, the declaratory judgment plaintiff asserted that the listing of patents in the Orange Book constitutes a threat to sue any ANDA filer who seeks approval for a competing generic product (*See* Doc. 1, Complaint, ¶ 65 and Doc. 34, Mylan memo at 1, 9, 14, 15 and 24), and that argument was expressly rejected by the Court of Appeals.

> Pfizer's compliance with the Hatch-Waxman listing requirement should not be construed as a blanket threat to potential infringers as far as Pfizer's patent enforcement intentions are concerned . . . . We are not prepared to hold that listing a patent in the Orange Book evinces an intent to sue any ANDA filer who submits a paragraph IV certification with respect to the patent.

Id. at 1333.

The close similarities between the two cases are evident from side-by-side comparison:

TEVA	MYLAN
Teva was not the first filer, having filed an ANDA and a "paragraph IV" certification after another generic had done so.	Mylan was not the first filer, having filed an ANDA and a "paragraph IV" certification after another generic had done so.

TEVA	MYLAN
Pfizer, the patentee, had listed patents in the Orange Book, including one patent covering the basic compound.	Merck, the patentee, had listed patents in the Orange Book, including one patent covering the basic compound.
In listing its patents in the Orange Book, Pfizer declared, as required by statute, that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug."	In listing its patents in the Orange Book, Merck declared, as required by statute, that "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use or sale of the drug."
Neither Teva nor any other ANDA filer sought to market before expiration of Pfizer's basic compound patent.	Neither Mylan nor any other ANDA filer sought to market before expiration of Merck's basic compound patent.
Neither Teva nor any other ANDA filer could go on the market until after Pfizer's basic compound patent expired.	Neither Mylan nor any other ANDA filer can go on the market until after Merck's basic compound patent expires.
The first ANDA filer was entitled to 180 days of marketing exclusivity after Pfizer's basic compound patent expired.	The first ANDA filer should be entitled to 180 days of marketing exclusivity after Merck's basic compound patent expires.

TEVA	MYLAN
If it had succeeded in its declaratory judgment action, Teva would have rendered the first filer's 180 day marketing exclusivity meaningless, thereby depriving the first filer of the incentive provided by Congress.	If it succeeds in its declaratory judgment action, Mylan could render the first filer's 180 day marketing exclusivity meaningless, thereby depriving the first filer of the incentive provided by Congress.
Teva requested a covenant not to sue and Pfizer declined.	Mylan requested a covenant not to sue (albeit, only after suit was brought) and Merck has declined.[5]
Pfizer did not respond at all to Teva's Paragraph IV notice letter.	Merck responded to Mylan's Paragraph IV notice letter by advising Mylan that Merck would not sue during the 45 day period.
Pfizer had sued other generics on other patents covering other products.	Merck has sued other generics on other patents covering other products.
Teva argued that the MMA created a new, relaxed standard for bringing declaratory judgment actions.	Mylan argues that the MMA created a new, relaxed standard for bringing declaratory judgment actions.

[5] Mylan's request did not come until September 28, 2005. *See* ¶ 3 of the Declaration (II) of Mary J. Morry under 28 U.S.C. § 1746 in Support of Defendant's Motion to Dismiss dated October 26, 2005 submitted herewith, ("Morry II decl."), long after the complaint had been filed and even after this motion had been brought. As such, it is not relevant to the issues before this Court. *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731, n.2 (Fed. Cir. 1988)("The presence or absence of jurisdiction must be determined on the facts existing at the time the complaint under consideration was filed.") *See also, Jervis B. Webb Co. v. Southern Sys., Inc.*, 742 F.2d 1388, 1398 (Fed. Cir. 1984).

TEVA	MYLAN
Pfizer sued the first ANDA filer, alleging infringement of the same patents as those certified by Teva and did so before the expiration of the 45 day grace period.	Merck did NOT sue the first ANDA filer (or any other ANDA filer), on any patent certified by Mylan, either before the expiration of the 45 day grace period or thereafter.

Mylan asserts that Merck "impermissibly ignores the totality of its conduct in favor of … addressing each fact in isolation from the other." (Doc. 34, Mylan memo at 13). Obviously, however, in assessing the totality of circumstances, each element must be evaluated individually, is precisely as the Court of Appeals did in the *Teva* case. It first discussed the individual elements and then, based on those evaluations, held that taken together they did not give rise to an objectively reasonable apprehension of being sued. Of the five factors relied upon by Teva (*See Teva*, 395 F.3d at 1331), four are precisely the same as those asserted here by Mylan, and the fifth is less favorable to Mylan. The patentee in *Teva* had sued the first generic filer on the same patents for which Teva sought a declaration. Merck has never sued anyone on the patents cited in the complaint here. In addition, here Merck gave an assurance to Mylan that no suit would be brought during the 45 day window.[6] That is more than Pfizer did in the *Teva* case.

[6] Contrary to Mylan's assertion, Merck's position is not that Mylan does not have a reasonable apprehension of being sued solely because of Merck's assurance (continued...)

None of those factors, taken individually or together, establish an objectively reasonable apprehension on the part of Mylan of being sued.

Mylan is in no better position to argue that it had a reasonable apprehension of suit than was Teva, and in at least one respect, Mylan is in a worse posture. When the Court of Appeals affirmed the dismissal of Teva's complaint for want of subject matter jurisdiction, it did so after considering all of these circumstances, both individually and in combination, and determining that they did not give rise to an objectively reasonable apprehension that suit would be brought. Because those facts were not sufficient to confer jurisdiction in *Teva*, they are equally insufficient to confer jurisdiction here.

D. Mylan Has Only Itself to Blame for its Predicament

Contrary to Mylan's assertion, this is not a case where Merck, or anyone else, is trying "to block all generic competition indefinitely." (Doc. 34, Mylan memo at 5). It is true that Mylan is precluded from getting FDA approval until December 2006, but that is because it did not challenge Merck's compound patent that does not expire until June 2006, after which Ivax, who certified earlier, is eligible for 180 days of marketing exclusivity. That, however, is consistent with

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(continued...)

that it would not bring suit within the 45-day period (*see* Doc. 34, Mylan memo at 12), but rather that Merck has done nothing to induce a reasonable apprehension.

the policy Congress implemented when it enacted the Hatch-Waxman Act. Congress provided an incentive to early generic filers, in the form of 180 days of marketing exclusivity. As Mylan correctly says, (Doc. 34, Mylan memo at 5) "[a]s an incentive for challenging patents, the first company to file a paragraph IV ANDA can receive a 180-day period of generic marketing exclusivity." Mylan filed its ANDA some two years after Ivax.

Generic competition will not be blocked indefinitely if Mylan's complaint is dismissed. Ivax, the first filer, can receive approval from the FDA to offer generic competition as soon as Merck's basic compound patent expires in June 2006, and Mylan could be finally approved by the FDA to market 180 days later, precisely as Congress intended.

Nor are Mylan's expenditures in connection with preparing its ANDA (Doc. 34, Mylan memo at 25) relevant here. Mylan made those expenditures and filed its ANDA with the full realization that its marketing would be subject to the rights of any earlier filer.

Moreover, those expenditures will not be wasted if Mylan's complaint is dismissed. Mylan made the expenditures because they were necessary to support its ANDA, for which it can receive marketing approval from the FDA when Ivax's period of exclusivity expires. Had Mylan not spent whatever amount it did spend on its ANDA, it could not come on the market at all. At most,

Mylan's return on that investment will be slightly delayed, and then only because Ivax acted more promptly.

E. Mylan's Reliance on Dr. Reddy's Situation Is Disingenuous

At least 15 times in its opposition brief, Mylan cites the fact that Merck sued Dr. Reddy's after the 45-day statutory period had expired. (*See* Doc. 34, Mylan memo at 2, 7, 9-10, 12, 15, 16, 17, 18, 19(2), 21, 24 and 25). But Mylan misleadingly omits the facts that the suit against Dr. Reddy's involves patents that are not any of those mentioned in Mylan's complaint and, further, that Dr. Reddy's is not seeking to market a generic version of Merck's PROSCAR® product, as is Mylan. Dr. Reddy's ANDA is for a different drug product, *i.e.*, a generic version of Merck's PROPECIA®, product which is prescribed for male pattern baldness. Mylan has not filed an ANDA seeking permission to market a generic version of the PROPECIA® product.

Instead of acknowledging these significant differences, Mylan obfuscates by referring generally to "finasteride patents" (*see* Doc. 34, Mylan memo at 7, 9, 10, 12, 18, 24 and 25), as if all "finasteride patents" were the same and all products in which finasteride is the active ingredient are used to treat the same conditions. They are not. Unlike the situation in *Teva*, where Pfizer sued Ivax but not Teva, two companies that were seeking to market generic versions of the same branded product covered by the same patents, here the only suit Merck

brought was on different patents against an ANDA filer that was seeking approval to market a generic version of a product that is different from the generic product Mylan is seeking to market. [7]

In further misdirection, Mylan refers to Dr. Reddy's as "one of Mylan's competitors," (Doc. 34, Mylan memo at 2, 9 and 25), implying that both companies are seeking to compete with respect to generic versions of the same Merck product. While Dr. Reddy's may be Mylan's competitor in the sense that they are both generic drug companies, Dr. Reddy's is seeking to market a generic version of Merck's PROPECIA® product while Mylan is seeking to market a generic version of Merck's PROSCAR® product, two products containing different amounts of finasteride that are prescribed for very different conditions.[8]

Mylan further obfuscates by asserting that "[t]his case involves finasteride tablets, which Merck sells under the brand-names PROSCAR® and PROPECIA®." Contrary to Mylan's implication, this case does not involve Merck's PROPECIA® product or any generic version thereof. The patents mentioned in Mylan's complaint are those that have been identified in the Orange

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[7] There is one patent, U.S. Patent 5,886,184, listed in the Orange book for both the PROSCAR® and PROPECIA® products. Merck did not sue Dr. Reddy's on that patent. Morry II decl. ¶ 7.

[8] Morry II decl. ¶ 8.

Book with respect to Merck's PROSCAR® product and Mylan's ANDA seeks only to obtain approval to market a generic version of that product.[9]

F. Merck Has Not Exhibited Any Pattern or Practice Which Could Give Mylan a Reasonable Apprehension of Suit

Mylan asserts that "Merck has engaged in a course of conduct demonstrating … a practice of waiting [until after the 45-day notice period under the Hatch-Waxman Act has expired] to sue…" (Doc. 34, Mylan memo at 17).[10] The only "evidence" of such a "course of conduct" or "practice" cited by Mylan is the Dr. Reddy's case. From this single instance, Mylan asks this Court to generalize to a "course of conduct" or an established "practice."

To buttress that argument, Mylan postulates a scheme where the patentee lies in wait until a generic company launches, then sues it for crippling damages. (Doc. 34, Mylan memo at 6-7). That is baseless speculation for at least two reasons. First, Merck in fact sued Dr. Reddy's well before it came on the market with a generic product and, hence before any damages could accrue. Second, it defies common sense to suggest that an innovator company would deliberately forgo the opportunity to block a generic company from selling an

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[9] *See* Morry II decl., ¶ 6.

[10] *See also*, Doc. 34, Mylan memo at 10 ("Merck's practice of delaying the on-set of litigation until after expiration of the 45 day Hatch-Waxman notice period….").

infringing product, allow that generic to come on the market, thereby decimating the innovator's profits, solely because it then hoped to recover, in a litigation, the profits it could have maintained by blocking the generic sales in the first place.

Significantly, in this case, Mylan mailed its "Paragraph IV" notice letter on April 26, 2005. If Merck had sued within the 45 day window, the 30 month stay on FDA approval of Mylan's ANDA would potentially run until December, 2007, a full year after Mylan can in fact, be free to get its FDA approval under the present circumstances, because Merck did not sue.

Rather than establishing a "wait and then sue" pattern, Merck's history is to the contrary. Mylan cites a number of litigations in which Merck has been involved. Only 33 of those were ANDA cases and of those 33, only one, the Dr. Reddy's case, was filed after the 45 day window had closed. (Morry II decl. ¶ 2). Thus, if Merck has an established "course of conduct" or "practice," it is to sue ANDA applicants during the 45-day notice period or not at all.

G. Sustaining Jurisdiction Over This Case Would Frustrate the Intent of Congress

For the first 25 pages of its opposition brief, Mylan tries to justify a contrived apprehension of suit that has no reasonable basis in fact and is merely a pretext for this suit. Mylan's real purpose surfaces at page 27, where it attempts to convince the Court that

> bringing a declaratory judgment suit, even if done solely for the purpose of triggering [an earlier ANDA filer's] generic exclusivity, is entirely consistent with Congressional intent.

"Triggering generic exclusivity" means trying to get a judicial decision that will prematurely start the early filer's (here, Ivax's) 180 days of marketing exclusivity so that it will run out before that company gets a chance to use it. As explained above, Ivax cannot market until June 2006 because neither it, nor any other generic company, challenged Merck's basic compound patent that remains in force until then. If Mylan can "trigger" that period now, Ivax's statutory exclusivity will have been dissipated before it can begin marketing.

It is bizarre to suggest that the same Congress that created the 180-day exclusivity period as an incentive for early ANDA filers simultaneously intended to allow later filers to destroy it by filing contrived declaratory judgment actions.

What Mylan seeks here is plain. Despite having no real fear of being sued, Mylan filed this suit, hoping that Merck would then agree to give a covenant not to sue to avoid the cost and inconvenience of pursuing a motion to dismiss.[11] Mylan would then proclaim itself the victor in a suit against the patent owner and demand that the FDA start the clock running on Ivax's exclusivity. (*See Teva*

[11] As noted above, Mylan did pursue that ploy by making a post-complaint request for a covenant not to sue as a condition for dismissing the case.

Pharmaceuticals USA, Inc. v. United States Food and Drug Admin., 182 F.3d 1003 (D.C. Cir. 1999).

The Generic Pharmaceutical Association ("GPhA"), a non-profit association of more than 140 manufacturers and distributors, filed an amicus brief in another *Teva v. FDA* case (*Teva Pharmaceuticals USA, Inc. v. Food and Drug Administration* [12]) in which the association argued that actions which would prematurely trigger the 180 day marketing exclusivity, as Mylan seeks to do here, should not be permitted.[13] As the GPhA said, if such actions are condoned, manufacturers will be:

> Free to bring "challenges" that, in fact, are designed to do no more than run out the clock on exclusivity before the generic can ever come to market. The result under both the pre-amended Hatch-Waxman Act and the MMA will be to discourage generic manufacturers from competing to get exclusivity in the first place, given the likelihood of their losing it before ever receiving its benefits.

Bosses Tab A at 4. This, according to the GPhA would

> Cut the legs out from under what Congress determined to be the appropriate incentive.

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[12] 2005 WL 2692489 (D.D.C. Oct. 21, 2005).

[13] Declaration of Stevan J. Bosses submitted herewith Tab A. That attempt, engineered by Mylan's counsel here, to destroy Teva's 180 days of exclusivity for the drug PRAVASTATIN®, was rejected in the District Court's October 21, 2005 decision. *Teva Pharmaceuticals USA, Inc. v. Food and Drug Admin.*, 2005 WL 2692489 (D.D.C. Oct. 21, 2005).

Id. And if such premature triggering were to be allowed it would

> Fuel precisely the type of Hatch-Waxman gamesmanship that Congress condemned when it reviewed the Act and passed the MMA.

Id. at 7.

Using a trumped-up apprehension of suit as an excuse to file a declaratory judgment action, solely to dissipate another generic company's prior marketing rights, is not consistent with the Congressional intent embodied in the Hatch-Waxman Act. More important, as the Federal Circuit made clear in the *Teva* decision, it is not a Constitutionally viable basis for a declaratory judgment action. *Teva*, 395 F.3d at 1338.

The criterion for subject matter jurisdiction here is whether Merck's conduct created in Mylan a reasonable apprehension that Merck would sue it on the patents listed in the complaint. It is Mylan's burden to prove that essential predicate. All that Mylan can point to here are facts that are indistinguishable from the controlling *Teva* decision, which compels dismissal.

H. Mylan's Cases are Readily Distinguishable

Although Mylan cites a large number of decisions, not one of those was decided after the Court of Appeals decision in *Teva*, although a simple review

of Shepard's reveals that there are at least two district court cases[14] which cite *Teva*. By virtually ignoring itself, *Teva*, and by failing to cite any cases decided thereafter, Mylan simply avoids acknowledging what is now settled law.

The decisions Mylan cites are readily distinguishable on other grounds as well. For example, most of the cases it cites are not ANDA cases, [15] and virtually all involved threat factors which do not exist in the present case. For example, several, including *Arrowhead, IvoclarVivadent, Inc. v. Hasel*, No. 02-CV-0316E(F), 2003 WL 21730520 (W.D.N.Y. June 30, 2003) ("Ivoclar"), *Nippon*,

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[14] *Citizen Electronics Co., Ltd. v. OSRAM GMBH*, 377 F. Supp. 2d 149 (D.D.C. 2005) and *Eon Labs, Inc. v. Pfizer Inc.*, 2005 U.S. Dist. LEXIS 14680 (S.D.N.Y. July 19, 2005). Both cases were dismissed for want of a justiciable controversy. One of those was an ANDA case which followed the decision in the *Teva* case.

[15] *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227 (1937); *Arrowhead Indus. Water, Inc. v. Ecolochem, Inc.*, 846 F.2d 731 (Fed. Cir. 1988); *Bennett v. Spear*, 520 U.S. 154 (1997); *B.P. Chems. Ltd. v. Union Carbide Corp.*, 4 F.3d 975 (Fed. Cir 1993) ("B.P."); *Clontech Labs., Inc. v. Life Techs., Inc.*, No. Civ.A. AW-00-1879, 2000 WL 33124811(D.Md., Dec. 20, 2000) ("Clontech"); *EMC Corp. v. Norand Corp*, 89 F.3d 807 (Fed. Cir. 1996) ("EMC"); *Fina Oil & Chem. Co. v. Ewen*, 123 F.3d 1466 (Fed. Cir. 1997); *Gen. Latex & Chem. Corp. v. BASF Corp.*, C.A. No. 99-038-SLR, 1999 U.S. Dist. LEXIS 22904 (D.Del. July 14, 1999); *Goodyear Tire & Rubber Co. v. Releasomers Inc.*, 824 F.2d 953 (Fed. Cir. 1987) ("Goodyear"); *Medtronic Inc. v. Am. Optical Corp.*, 327 F. Supp. 1327 (D.Minn. 1971) ("Medtronic"); *Millipore Corp. v Univ. Patents, Inc.*, 682 F.Supp. 227 (D.Del. 1987); *Nippon Elec. Glass Co. v. Sheldon*, 489 F. Supp. 119 (S.D.N.Y. 1980)("Nippon"); *Northeastern Fla. Chapter of the Associated Gen. Contractors of Am.*, 508 U.S. 656 (1993); *Stone v. INS*, 514 U.S. 386 (1995); *Super Prods. Corp. v. D P Way Corp.*, 546 F.2d 748 (7th Cir. 1997) and *Vanguard Research, Inc. v. Peat, Inc.*, 304 F.3d 1249 (Fed. Cir. 2002)("Vanguard").

Sigma-Tau Industrie Farmaceutiche Riunite, S.p.A. v. Lonza, Ltd., 36 F. Supp. 2d. 26 (D.D.C. 1999) ("Sigma-Tau") and *Vanguard*, involved express threats of infringement litigation by the patentee directed to customers of the declaratory judgment plaintiff. In others, including *EMC*, *DuPont Merck Pharm. Co. v. Bristol-Myers Squibb Co.*, 62 F.3d. 1397 (Fed. Cir. 1995) and *Medtronic*, the patentee had written threatening letters to the alleged infringer. Some, including *B.P.*, *Goodyear*, *Clontech*, and *Kos Pharms., Inc. v. Barr Labs., Inc.*, 242 F. Supp. 2d. 311 (S.D.N.Y. 2003) were cases where the patentee had already sued the alleged infringer on the same patents or technology covering the same product. In *Arrowhead* and *Ivoclar*, the patentee had already instituted litigation against third parties on the identical patents. And in *Sigma-Tau* and *Teva Pharms, USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819 (N.D.Ill. 2004) there had already been instituted foreign litigation between the patentee and the alleged infringer (or its related company) involving the foreign counterpart to the U.S. patent.

CONCLUSION

For the reasons set forth in Merck's opening brief as well as those set forth above, Mylan's complaint should be dismissed.

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Respectfully submitted,

s/ Brian P. Downey

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CERTIFICATE OF COMPLIANCE

Merck & Co., Inc, hereby certifies that its Reply Memorandum of Law in Support of Defendant's Motion to Dismiss Plaintiff's Complaint complies with the word count requirement of this Court's order dated October 26, 2005 The word count of the Brief is 5,191 words (excluding the tables of authority and contents).

s/ Brian P. Downey

CERTIFICATE OF SERVICE

I hereby certify that on October 26, 2005, a copy of the foregoing reply brief was filed electronically and should be served upon the following individuals through the Court's Electronic Case Filing (ECF) system:

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